



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

San Juan District
Compliance Branch
466 Fernández Juncos
San Juan, Puerto Rico 00901-3223

Telephone: 787-474-9500
FAX: 787-729-6658

April 29, 2004

WARNING LETTER
SJN-04-06

Certified Mail
Return Receipt Requested

Mr. Ricardo Panneflek
President
Home Shopping Services, Inc.
D/b/a Mundo Natural
P.O. Box 810288
Carolina, Puerto Rico 00981

Dear Mr. Panneflek:

On December 29, 2003 and January 5, 2004, investigators from the Food and Drug Administration (FDA) inspected your facility located at Avenida Campo Rico 881, San Juan, Puerto Rico. During our investigation, the investigator collected labeling for your products "Noni Juice Liquid Herbal Supplement" and "Noni Cleansing Formula AM/PM" from a dealer that stocks your products. The labeling collected by our investigator includes product labels and promotional materials distributed with your products, which are marketed under the brand name "Mundo Natural."

Our review of your "Noni Juice Liquid Herbal Supplement" and "Noni Extra Strength Cleansing Formula AM/PM" product labels and the "New Noni Products" brochure found claims that these products are useful in the treatment and cure of diseases. These labeling claims cause "Noni Juice Liquid Herbal Supplement" and "Noni Extra Strength Cleansing Formula AM/PM" to be drugs, as defined in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act and FDA regulations through links on FDA's Internet home page at www.fda.gov.

Claims made on the label of your Noni Juice Liquid Herbal Supplement include:

- Noni has been used to treat Diabetes, ... Asthma, Cataracts, Colds, High Blood Pressure, ... Breast Cancer, Depression, Migraine, ... Stroke, Tumors, Infections, Gastric Ulcers, ... Prostate Cancer, ... Cancer, ... Arthritis, ... Chest Infections,

Claims made in Spanish within your brochure entitled "New Noni Products", when translated to English, include:

- Noni is a tropical fruit recognized worldwide for its curing attributes. For thousands of years Noni has been utilized in the treatment of diseases such as arthritis, high [blood] pressure, prostate inflammation, diabetes, high cholesterol, ... and migraine.

Claims made in Spanish on the label of your "Noni Cleansing Formula AM/PM" product, when translated to English, include:

- Noni is a tropical fruit recognized worldwide for its curing attributes. For thousands of years Noni has been utilized in the treatment of diseases such as arthritis, high [blood] pressure, prostate inflammation, diabetes, high cholesterol, ... and migraine.

Because these products are not generally recognized as safe and effective when used as indicated in their labeling, they are "new drugs" as defined under section 201(p) of the Act. Therefore, under section 505(a) of the Act, these products may not be legally marketed in the United States without an approved New Drug Application.

This letter is not meant to be an all-inclusive list of deficiencies in your products and their labeling. Other violations can subject the products to legal action. It is your responsibility to ensure that all of your products are manufactured and labeled in compliance with all applicable statutes and regulations enforced by FDA.

You should take prompt action to correct the above-referenced violations. Failure to promptly correct these violations may result in regulatory action without further notice. The Act provides for the seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. You may wish to include in your response documentation such as revised labels or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within 15 working days, state the reasons for the delay and the time frame within the corrections will be completed.

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Your written reply to these concerns should be directed to the Food and Drug Administration, attention: Rafael Nevárez, Compliance Officer, at 466 Fernández Juncos Avenue, San Juan, Puerto Rico 00901-3223. If you have any questions regarding any issue in this letter, please contact Mr. Nevárez at (787) 474-9545.

Sincerely,



Donald J. Voeller
District Director
San Juan District

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